Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effects of Swedish Massage on Functional Balance, Proprioception, Active and Passive Ankle Range of Motion, and Sensory Neuropathic Symptoms in Patients with Type 2 Diabetes Mellitus and Peripheral Neuropathy: A Randomized Controlled Trial

Protocol summary

Study aim

To assess the effects of Swedish massage plus standard care on balance, ankle proprioception, ankle range of motion, and sensory neuropathic symptoms in patients with type 2 diabetes and peripheral neuropathy.

Design

Single center, two arm, parallel group randomized controlled trial; 64 participants, 32 per group. Stratified block randomization, 1:1, by sex and diabetes duration, with variable block sizes of 4 and 6. Allocation concealed using opaque, sealed, numbered envelopes. Assessors, data collectors, and statistician blinded. Phase not applicable.

Settings and conduct

Endocrine and Metabolism Research Center, Isfahan University of Medical Sciences, Iran. Assessments will occur at baseline, after session 3, week 4, and one month later. Metabolic measures and blood pressure will be assessed at baseline and week 4. Participants and therapist cannot be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men and women aged 55 to 75 years; diabetes duration 5 to 25 years; confirmed peripheral neuropathy; glycated hemoglobin 7% to 9.5%; stable medication for at least 8 weeks; willingness to participate. Exclusion criteria: deep vein thrombosis, severe peripheral arterial disease, active foot ulcer or infection, severe Charcot disease, major lower limb deformity or recent surgery, other neurological disease affecting balance, stage 4 or 5 kidney disease, or massage or manual therapy within 3 months.

Intervention groups

Intervention Group: Swedish massage from lower legs to toes, 30 minutes per session, three times weekly for 4 weeks, plus standard care. Control: standard medical treatment and routine care without massage.

Main outcome variables

Primary outcome: Functional balance based on the TUG test. Secondary outcomes: Michigan questionnaire score; severity of sensory symptoms based on the Visual Analog Scale (VAS); ankle proprioception based on the joint position reproduction test; active and passive ankle range of motion; glycosylated hemoglobin; lipid profile; blood pressure.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260616069824N1**
Registration date: **2026-11-21, 1405/08/30**
Registration timing: **registered_while_recruiting**

Last update: **2026-11-21, 1405/08/30**
Update count: **0**

Registration date

2026-11-21, 1405/08/30

Registrant information

Name

Mohammad hadi Salavati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3236 3868

Email address

mohammadhadisalavati78@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date
2026-11-21, 1405/08/30
Expected recruitment end date
2027-02-04, 1405/11/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of Swedish Massage on Functional Balance, Proprioception, Active and Passive Ankle Range of Motion, and Sensory Neuropathic Symptoms in Patients with Type 2 Diabetes Mellitus and Peripheral Neuropathy: A Randomized Controlled Trial

Public title
Effect of Swedish Massage on Balance and Nerve Symptoms in Patients with Type 2 Diabetes and Peripheral Neuropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 55 and 75 years. Both male and female patients. Confirmed diagnosis of type 2 diabetes mellitus. Diabetes duration between 5 and 25 years. Confirmed diabetic peripheral neuropathy (MNSI score ≥ 7). HbA1c between 7% and 9.5%. Stable medication regimen for at least 8 weeks before enrollment. Ability and willingness to participate and complete follow-up.
Exclusion criteria:
History of deep vein thrombosis or severe peripheral arterial disease (ABI < 0.8). Active wound, infection, or severe Charcot neuroarthropathy. Severe joint deformity or recent major lower limb surgery. Non-diabetic neurological diseases affecting balance. Stage 4 or 5 renal failure (eGFR < 30 mL/min/1.73m²). Receiving massage or manual physiotherapy in the past 3 months. Known allergy to almond or nut oils (massage oil).
Age
From **55 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Method of Randomization: Stratified permuted block randomization with a 1:1 allocation ratio. Stratification will be based on two factors: sex (male/female) and diabetes duration (5–15 years vs. 16–25 years), yielding four strata. Within each stratum, variable block sizes of 4 and 6 will be used. Unit of Randomization: Individual (each eligible patient is randomized independently). Tools Used: Random Allocation Software will be used for sequence generation. Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE) will be used for allocation concealment. Sequence Construction: The sequence will be generated by an independent researcher not involved in screening, intervention, or outcome assessment, using a random seed to ensure a reproducible audit trail. Allocation Concealment: Strictly enforced. The independent researcher will generate the sequence and prepare the sealed envelopes. Envelopes will be opened sequentially only after participant eligibility is confirmed and baseline assessments are completed.
Blinding (investigator's opinion)
Single blinded
Blinding description
This is a single-blind (outcome assessor–blinded) randomized controlled trial. Because the intervention is a physical therapy (Swedish massage), participants and the care provider cannot be blinded; this is acknowledged, and participants are fully informed of their allocation at consent. The outcome assessor and data collector are blinded; blinding is achieved by independent sequence generation and SNOSE preparation by a researcher not involved in screening, intervention, or assessment; envelope opening only after eligibility confirmation and completion of baseline assessments; assessments performed in a separate room with no access to allocation lists or the massage room; use of participant ID codes only on all forms and the electronic database; instruction to participants not to disclose their group; and documentation of any inadvertent unblinding. The data analyser is also blinded: the locked dataset is transferred with groups coded as "Group A" and "Group B," all analyses including MMRM are run on coded labels, and unblinding occurs only after the primary analysis is completed and signed off. Manuscript writers receive only unblinded aggregate results.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of the "Alzahra Research Centers
Street address
Hezar jerib street
City
Isfahan

Province
Isfehan
Postal code
۷۳۴۶۱-۸۱۷۴۶
Approval date
2026-06-10, 1405/03/20
Ethics committee reference number
IR.ARI.MUI.REC.1405.084

Health conditions studied

1

Description of health condition studied
Type 2 diabetes
ICD-10 code
E08.21
ICD-10 code description
Diabetes mellitus due to underlying condition with diabetic nephropathy

Primary outcomes

1

Description
Functional balance, assessed by the mean time required to complete the Timed Up and Go test, measured in seconds.
Timepoint
At baseline (before intervention), after the third massage session (or the corresponding time point in the control group), immediately after completion of the 4-week intervention, and one month after intervention completion.
Method of measurement
Timed Up and Go test. The time required to complete the test will be measured and recorded in seconds.

Secondary outcomes

1

Description
Michigan Neuropathy Screening Instrument questionnaire score, ranging from 0 to 15.
Timepoint
At baseline before intervention, after the third massage session (or the corresponding time point in the control group), at the end of the 4 week intervention, and one month after intervention completion.
Method of measurement
Michigan Neuropathy Screening Instrument questionnaire. The total questionnaire score will be calculated and recorded.

2

Description
Severity of sensory neuropathic symptoms, measured using a Visual Analogue Scale, with scores ranging from 0 to 10.
Timepoint
At baseline before intervention, after the third massage session (or the corresponding time point in the control group), at the end of the 4 week intervention, and one month after intervention completion.
Method of measurement
Visual Analogue Scale for assessing the severity of sensory neuropathic symptoms. Symptoms will be assessed and scored on a 0 to 10 scale.

3

Description
Ankle proprioception, assessed by the Joint Position Reproduction test and recorded in degrees.
Timepoint
At baseline before intervention, after the third massage session (or the corresponding time point in the control group), at the end of the 4 week intervention, and one month after intervention completion.
Method of measurement
Joint Position Reproduction test for evaluating ankle proprioception. Measurements will be recorded in degrees.

4

Description
Active range of motion of the ankle joint, measured in degrees.
Timepoint
At baseline before intervention, after the third massage session (or the corresponding time point in the control group), at the end of the 4 week intervention, and one month after intervention completion.
Method of measurement
Goniometer measurement of active ankle joint range of motion, recorded in degrees.

5

Description
Passive range of motion of the ankle joint, measured in degrees.
Timepoint
At baseline before intervention, after the third massage session (or the corresponding time point in the control group), at the end of the 4 week intervention, and one month after intervention completion.
Method of measurement
Goniometer measurement of passive ankle joint range of motion, recorded in degrees.

6

Description
Blood pressure level, measured in millimeters of mercury.
Timepoint
At baseline before intervention and at the end of the 4 week intervention.
Method of measurement
Blood pressure measurement, with values recorded in

millimeters of mercury.

7

Description
Laboratory metabolic parameters, including glycated hemoglobin, total cholesterol, triglycerides, high density lipoprotein cholesterol, and low density lipoprotein cholesterol.

Timepoint
At baseline before intervention and at the end of the 4 week intervention.

Method of measurement
Laboratory measurement of glycated hemoglobin, total cholesterol, triglycerides, high density lipoprotein cholesterol, and low density lipoprotein cholesterol. Glycated hemoglobin will be reported as a percentage and lipid parameters in milligrams per deciliter.

Intervention groups

1

Description
Intervention group: Participants will receive Swedish massage in addition to standard medical treatment. Massage will be applied from the lower legs to the toes for 30 minutes per session, three times per week for 4 weeks (12 sessions in total).Each session will include six sequential techniques: effleurage (10 minutes), consisting of gentle long strokes directed toward the heart; petrissage (10 minutes), involving gentle kneading, compression, and rolling movements; friction (5 minutes), involving circular movements over muscles and plantar fascia, avoiding bones; tapotement (2 minutes), using light rhythmic tapping, omitted in case of discomfort or fragile skin; vibration (2 minutes); and final effleurage (1 minute). Sweet almond oil will be used to reduce friction. Participants will be screened for almond allergy. Before each session, the lower limbs will be examined for skin injuries, edema, acute inflammation, or infection. Massage pressure will be gradually adjusted according to individual tolerance. Massage will be performed by a trained and certified therapist experienced in Swedish massage and diabetic neuropathy precautions.

Category
Treatment - Other

2

Description
Control group: Participants will continue their standard medical treatment and routine care prescribed by their treating endocrinologist throughout the study period. No massage intervention will be provided. Medications used for glycemic control, blood pressure, lipid management, and other related conditions will be continued and recorded.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan Endocrine and Metabolism Research Center

Full name of responsible person
Mohammad Hadi Salavati

Street address
Khorram Street, Jomhouri Square

City
Isfahan

Province
Isfehan

Postal code
81876-98191

Phone
+98 913 800 6518

Email
mohammadhadisalavati78@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Gholamreza Asgari

Street address
Building No. 4, Hezar jerib street, Isfahan

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Phone
+98 31 3668 5149

Email
research@mui.ac.ir

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Esfahan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Mohammad Hadi Salavati

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Sport Sciences

Street address
Isfahan Endocrine and Metabolism Research Center, Sedigheh Tahereh Comprehensive Rehabilitation and Medical Center, Khorram Street, Jmohouri Eslami Square

City
Isfahan

Province
Isfehan

Postal code
8187698191

Phone
+98 913 800 6518

Email
mohammadhadisalavati78@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Mohammad Hadi Salavati

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

Street address
Hezar Jarib Street

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Phone
+98 913 800 6518

Email
mohammadhadisalavati78@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Mohammad Hadi Salavati

Position
Researcher

Latest degree
Master

Other areas of specialty/work
Rehabilitation management

Street address
Hezar Jarib Street

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Phone
0098 31 2363868

Email
mohammadhadisalavati78@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available